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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,629	09/23/2003	James P. Delaney	10123/03501	2181

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EXAMINER

JOHNSON, JERROLD D

ART UNIT	PAPER NUMBER
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3728

DATE MAILED: 03/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

8N

Office Action Summary	Application No. 10/668,629	Applicant(s) DELANEY ET AL.	
	Examiner Jerrold Johnson	Art Unit 3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/27/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the hydration opening that produces the desired ratio of one to one, as is claimed in claim 9, and where the hydration opening is substantially equidistant from the first and second ends, as is claimed in claim 10, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 recites the limitation "the hydrating fluid" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Additionally, claim 18 is directed to a method step of dividing the fluid, but the claim is not correctly set forth as a hybrid claim of a method claim depending from a product claim. Correction is required.

Claim 14 recites a one to one ratio of flow. Claim 14 depends from claim 13 which depends on claim 12. Claim 12 recites a different amount of flow at the first end from the second end. Accordingly, claim 14 is indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 1-9, 12, 13, and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Ullman US 6,569,106.

Re claim 1, Ullman discloses in Fig. 4 a protective package for an elongated medical device, comprising:

a protective sheath 27 including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device, and

a hydration opening disposed between the first and second ends of the sheath.

Re claim 2, the sheath is formed as a hoop and wherein the medical device is a catheter. Note Col. 3 lines 29 and 30. Additionally, small ended catheters, such as are shown by Talonn US 3,606,001, which herein serves as extrinsic evidence, are representative of a type of catheter which would require little, if any modification to the protective package of Ullman to accommodate.

Re claim 3, a protective assembly 18 is disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end.

Re claim 4, a luer 30 is attached to the sheath in fluid contact with the lumen, the luer defining the hydration opening.

Re claim 5, an adapter 30 is coupled to the hydration opening capable of receiving a syringe.

Re claim 6, the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device, through the size of the funnel shaped opening 18, which would accommodate the distal end.

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Re claim 7, the sheath is adapted to contain one of a catheter, a guide wire and a medical coil.

Re claim 8, the sheath is adapted to contain a catheter with a shaped distal tip. Again, reference is made to the funnel opening, which may or may not be needed to accommodate a shaped distal tip, as the shaped distal tip of some catheters is of a size that approximates the size of the remainder of the catheter, as is shown in Talonn.

Re claim 9, the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 12, the hydration opening appears to be oriented to direct an amount of flow toward the first end which is different than an amount of flow directed toward the second end.

Re claim 13, the hydration opening is positioned so that, the difference in the amounts of flow toward the first and second ends achieves a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 15, Ullman discloses a catheter kit comprising
a catheter having a shaped distal tip;
a tubular enclosure 27 having a length and an inner diameter corresponding, respectively, to a length and outer diameter of the catheter;
a first end of the tubular enclosure 18,21 being adapted to receive the shaped distal tip;
a second end of the tubular enclosure being adapted to receive a proximal end of the catheter, and

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a hydration opening 30 extending into an interior of the tubular enclosure between the first and second ends thereof, the hydration opening being positioned so that a desired proportion of flow thereinto is directed toward the first and second ends.

Re claim 16, a protective structure 18,21 is disposed at the first end, the protective structure maintaining a desired curvature of the shaped distal tip.

Re claim 17, the tubular enclosure is coiled to form a hoop.

2. Claims 1-7 and 9-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Samuels US 6,588,588.

Re claim 1, Samuels discloses in a protective package for an elongated medical device, comprising:

a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device, and

a hydration opening 10 disposed between the first 42 and second 46 ends of the sheath.

Re claim 3, a protective assembly the inside of the lumen 10 is disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end.

Re claim 4, a luer 10 is attached to the sheath in fluid contact with the lumen, the luer defining the hydration opening.

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Re claim 5, an adapter 10 is coupled to the hydration opening capable of receiving a syringe.

Re claim 6, the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device.

Re claim 7, the sheath is adapted to contain one of a catheter, a guide wire and a medical coil.

Re claim 9, the hydration opening 10 is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 10, the desired ratio is one to one. The one to one ratio is achieved as the flow of fluid into the first end will necessarily flow through the second end, as the ends are connected.

Re claim 11, the hydration opening is substantially equidistant from the first and second ends.

Re claim 12, the hydration opening is oriented to direct a greater amount of flow toward the first end which is than an amount of flow directed toward the second end. The flow is initially directed toward the first end 42, but thereafter the desired ratio of fluid flow at the first end and second end will be equalized as the fluids flow through the sheath toward the other ends, achieving one to one flow upon the filling of the sheath.

Re claim 13, the hydration opening is positioned so that, the difference in the amounts of flow toward the first and second ends achieves a desired ratio of fluid flow at the first end to fluid flow at the second end.

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Re claim 14, the desired ratio is one to one.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 8, and 15-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samuels US 6,588,588 in view of Ullman.

Samuels, as stated above, discloses the claimed features of claims 1-7 and 9-14, but does not disclose his package being used with a catheter.

Samuels further discloses the structure of the package as claimed with the sheath being formed as a hoop but does not disclose the medical device is a catheter.

Again, Ullman discloses in col. 3 lines 29 and 30 the use of a guidewire package being used to protect and hydrate catheters.

It would have been obvious to one of ordinary skill in the art to modify the package of Samuels, as Ullman suggests, to accommodate catheters. Additionally, small ended catheters, such as are shown by Talonn US 3,606,001, which herein serves as extrinsic evidence, are representative of a type of catheter which would require little, if any modification to the protective package of Samuels to accommodate a catheter. There are inherent benefits brought on when the uses of an item, such as is disclosed by Samuels, are increased, as would be the case upon the slight modification of the package of Samuels suggested by Ullman.

Additionally, the sheath of Samuels would easily be adapted to contain a catheter with a shaped distal tip upon the modifications as taught by Ullman. Again, reference is made to the catheter of Talonn. Modifications may or may not be needed to accommodate a shaped distal tip in many catheters, like that disclosed by Talonn. This is because the shaped distal tip of some catheters, such as is disclosed by Talonn, are of a size that approximates the size of the remainder of the catheter.

Additionally, upon the filling of the sheath of Samuels with fluid, the proximal and distal ends are substantially equally hydrated. And, as was previously stated, the hydration opening is equidistant between the first and second ends.

4. Claims 1,3,6-9,12,13,15,16 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Taniguchi US 3,861,395.

Re claim 1,15 and 19, Taniguchi discloses (best seen in Figs. 1 and 3) a protective package for an elongated medical device (the micro-catheter), comprising:

a protective sheath including a lumen sized to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device, and

a hydration opening (beneath the reservoir 31, as seen in Fig. 3) disposed between the first end not identified and second 22 ends of the sheath. The proximal end 66 of the catheter is shown being extended past the second end 22 during use in Fig. 1, and recessed behind the second end 22 in Fig. 3).

Re claim 3, a protective assembly (not identified) is disposed at the first end of the sheath, the protective assembly being adapted to maintain a desired shape of the distal end.

Re claim 6 and 16, the protective assembly is adapted to prevent damage to a curvature of the distal end of the elongated medical device.

Re claim 7, the sheath is adapted to contain one of a catheter, a guide wire and a medical coil.

Re claim 9, the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 12, the hydration opening is oriented to direct a greater amount of flow toward the first end which is than an amount of flow directed toward the second end.

Re claim 13, the hydration opening is positioned so that, the difference in the amounts of flow toward the first and second ends achieves a desired ratio of fluid flow at the first end to fluid flow at the second end.

5. Claims 4 and are rejected under 35 U.S.C. 103(a) as being unpatentable over Taniguchi US 3,861,395 in view of Hodgkins US 4,805,611.

Taniguchi discloses the claimed features but does not disclose a luer or adapter capable of receiving a syringe.

Hodgkins discloses a luer or adapter 67 capable of receiving a syringe.

It would have been obvious to one of ordinary skill in the art to modify the sheath of Taniguchi with the much simpler construction of an irrigation port as taught by Hodgkins so as to allow the use of syringes to administer a desired amount and type of irrigation compound or lubricant.

6. Claims 1,4,7,9,10 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Laak US 5,597,264.

Re claim 1, Laak discloses on the first page of the patent a protective package capable of accommodating an elongated medical device, comprising:

a protective sheath disposed between end caps 14b including a lumen of a size that is capable to receive a body of the elongated medical device, wherein a first end of the sheath is adapted to receive a distal end of the elongated medical device and a second end of the sheath is adapted to receive a proximal end of the elongated medical device, and

a hydration opening 12 disposed between the first and second ends of the sheath.

Re claim 4, a luer 12 is attached to the sheath in fluid contact with the lumen, the luer defining the hydration opening.

Re claim 7, the sheath is easily of a size such that it is adapted to contain one of a catheter, a guide wire and a medical coil.

Re claim 9, the hydration opening is adapted to divide a flow of the fluid thereinto to achieve a desired ratio of fluid flow at the first end to fluid flow at the second end.

Re claim 10, the desired ratio is one to one. The one to one ratio is achieved as the flow of fluid into the first end will necessarily flow through the second end, as the ends are connected.

Re claim 11, the hydration opening is substantially equidistant from the first and second ends.

Note that the claims 1,4,7,9,10 and 11 are of such breadth so as to read on a variety of structures like Laak, which both disclose the structure defined therein, as well as meeting the standard of being capable of providing the intended use described therein.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerrold Johnson whose telephone number is 571-272-7141. The examiner can normally be reached on 9:30 to 6:00 M-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JDJ

A handwritten signature in black ink, appearing to read 'Mickey Yu', with a stylized, flowing script.

Mickey Yu
Supervisory Patent Examiner
Group 3700